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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Bell, et al  
SERIAL NO.: 09/794,576 GROUP ART UNIT: 1645  
FILED: February 27, 2001 EXAMINER: Zeman, Robert A.  
FOR: THERAPEUTIC CALCIUM PHOSPHATE PARTICLES AND  
METHODS OF MANUFACTURE AND USE

Attorney Docket No. 37070/254251

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I, Edgar H. Relyveld, declare as follows:

1. I have over 50+ years of experience in pharmaceutical sciences, including 50 years of experience researching the manufacture and use of calcium phosphate particles.
2. I am knowledgeable about the calcium phosphate particles disclosed in the present patent application, assigned to BioSante Pharmaceuticals, Inc. ("BioSante").
3. I am the named inventor on U.S. Patents 3,983,229, 4,016,252, 4,070,454, 4,075,321, 4,350,686, 4,552,756, 4,625,019 and 5,318,913. Copies of these patents are attached behind Exhibit A.

4. BioSante has asked me to review and compare the above-identified application ("the Application") with the calcium phosphate particles disclosed in my patents. I have reviewed the Application and the calcium phosphate particles disclosed in my patents. In particular, I have compared the calcium phosphate particles disclosed in the Application to those disclosed in U.S. Patent 4,016,252 (the "'252 Patent"), issued to me.
5. The Application discloses calcium phosphate particles with a diameter ranging from 300 nm to 4000 nm that are optionally coated (either partially or fully) with an antigenic material. The calcium phosphate particles disclosed in the Application may be used in vaccine compositions comprising the particles and a pharmaceutically acceptable carrier or other excipient. The Application also discloses methods of making the calcium phosphate particles and methods of using the particles as vaccine adjuvants.
6. The calcium phosphate particles disclosed in the Application are different from the calcium phosphate particles disclosed in the '252 Patent.
7. Unlike the present invention, the '252 Patent does not disclose calcium phosphate particles that are "substantially smooth" or "substantially spherical." Despite efforts, I was unable to obtain the "substantially smooth" or "substantially spherical" calcium phosphate particles of the present invention. The inventors of the Application were able to obtain these results through their novel manufacturing technique.

8. The novel morphology of the calcium phosphate particles of the present invention result in greater control over the degree of antigenic material saturation which can be achieved in the particle. This control leads to greater efficiency in particle production and efficacy in treatment using the particles.
9. The Action is incorrect in stating that the particles in the '252 Patent are "of the same composition and the same size" as the calcium phosphate particles of the present invention.
10. I declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true, and further that the foregoing statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

Date: Nov. 18<sup>th</sup> 2004 Signed: 

Edgar Hans Relyveld